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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/058,945  | 01/30/2002  | Thomas Hermann       | 215482US0X                   | 5458             |
| 22850   | 7590        | 01/30/2004           |                              |                  |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>KERR, KATHLEEN M |                  |
|   |             |                      | ART UNIT<br>1652             | PAPER NUMBER     |

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/058,945

**Applicant(s)**

HERMANN ET AL.

**Examiner**

Kathleen M Kerr

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 7-9,23-26 and 28-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,10-22,27 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/13/02 . 6) ☒ Other: *taxonomy browser, alignments*.

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a written restriction requirement (mailed on October 3, 2003), Applicants filed an election received on November 3, 2003. Claims 1-45 are pending in the instant Office action.

### ***Election***

2. Applicant's election with traverse of Group I, Claims 1-6, 10-22, 27, and 42-45 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)). The requirement is therefore made FINAL.

Claims 1-45 are pending in the instant application. Claims 7-9, 23-26, and 28-41 are withdrawn from consideration as non-elected inventions. Claims 1-6, 10-22, 27, and 42-45 will be examined herein.

### ***Priority***

3. The instant application is granted the benefit of foreign applications 10103873.9 and 10110760.9 filed in Germany on January 30, 2001 and March 7, 2001, respectively. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Said papers are in German. While this foreign priority is granted, the claims cannot be granted either of these filing dates without a certified translation of the priority document(s) since support in the priority document cannot be ascertained.

Thus, the earliest effective filing date of the claims examined herein is January 30, 2002.

***Information Disclosure Statement***

4. The information disclosure statement filed on May 13, 2002 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. Corrections made by the Examiner will appear in the citations on the front of any patent granted from the instant application.

***Declaration***

5. It is noted that the signed declaration file May 13, 2003 notes that the specification is "attached hereto". While this is not the case, with the specification having been filed on January 30, 2002, the declaration is clearly set forth for the instant application by means of the title and inventors as well as the docket number in the upper left corner. No action is required by applicants.

***Objections to the Specification***

6. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species, *Corynebacterium glutamicum*, and the enzyme name, trehalose 6-phosphate synthase, for completeness.

7. The specification is objected to for lacking updated U.S. patent application citations. On page 27, line 2, an application is cited that is now a U.S. patent 6,586,214. Correction is required.

***Objections to the Claims***

8. Claims 2 and 18 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. SEQ ID NO:2 is disclosed in the instant specification as having trehalose 6-phosphate synthase activity; thus, this feature is inherent in the polynucleotide of Claims 1 and 11 and cannot further limit the subject matter of the claim.

9. Claims 5, 6, 21 and 22, are objected to for using an improper genus/species name. In Claims 5 and 21, “*Coryneform*” in italics indicates a genus name; however, this is a vernacular name for the genus ---*Corynebacterium*---. In Claims 6 and 22, “*Coryneform glutamicum*” should be ---*Corynebacterium glutamicum*---. Correction is required.

10. Claim 12 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 is drawn to SEQ ID NO:1, which is described as a DNA sequence – DNA being a double stranded molecule. Thus, a “complimentary” polynucleotide in no way further limits the DNA. For proper further limiting parameters, the claim must be drawn to a polynucleotide that is the full complement of the coding strand of SEQ ID NO:1.

11. Claims 13-17 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

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cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of Claims 13-15 broadens the subject matter of Claim 11 by allowing alterations within SEQ ID NO:1 (within a certain % identity). Claim 16 broadens Claim 11 by requiring only a short oligomer of SEQ ID NO:1 and not the full-length sequence. Claim 17 broadens Claim 11 by claiming any polynucleotide that hybridizes to SEQ ID NO:1. Each of the claims can be rewritten as independent claims for correct claim structure; the instant claims will be examined as if they are independent claims related to SEQ ID NO:1.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 6 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush group is unclear because it contains overlapping members. The species “*Brevibacterium lactofermentum*” and “*Brevibacterium divaricatum*” are synonyms for ---*Corynebacterium glutamicum*--- (see attachment of Taxonomy Browser), already in the Markush group. Thus, the nature of these two species is unclear. All other species are clearly found in the art by means of the Taxonomy Browser and/or the ATCC collection. Correction is required.

13. Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. The term “washing”, which relates conditions, is confusing in view of the specification and the art. These very low stringency conditions are typically used in a hybridization step (allowing everything to stick) followed by a more stringent washing step that removes “false-positives”. Moreover, on page 18, these conditions are noted as hybridization conditions, not wash conditions. Clarification is required.

14. Claims 42-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “consisting essentially of” is confusing in its usage in the instant claims; no definition of this transitional phrase as it is applied to polynucleotides is found in the specification. As found in M.P.E.P. § 2111.03:

“A consisting essentially of” claim occupies a middle ground between closed claims that are written in a consisting of” format and fully open claims that are drafted in a comprising” format.” PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988).”

Since even the most open language, “comprising” language, with respect to polynucleotide sequences is specific for the sequence from end-to-end (i.e., no alterations within SEQ ID NO:1), a claim that is less open as governed by the “consisting essentially of” language also cannot have changes within the sequence. Since “absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising” (see M.P.E.P. § 2111.03), the instant claims are read as “comprising” which would render them identical to Claims 11, 19, 20, and 27, respectively.

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Thus, the meaning of “consisting essentially of” in Claim 42 is confusing. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-17 are drawn to polynucleotides having at least 70% identity with or having a consecutive fragment of SEQ ID NO:1; no function of the claimed polynucleotide is a limitation in the instant claims.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the



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common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification describes polynucleotides encoding OtsA, trehalose 6-phosphate synthase polypeptides. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having trehalose 6-phosphate synthase activity). However, the genus of the instant claims also contains polynucleotides within the sequence identity or fragment limitations, but having different function. Applicants have not fully described a genus that has sequence identity or fragment limitations in the absence of functional limitations.

16. Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that encode SEQ ID NO:2, does not reasonably provide enablement for polynucleotides structurally related to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. To use such polynucleotides would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of

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experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification describes a polynucleotide (SEQ ID NO:1) that encodes SEQ ID NO:2, a trehalose 6-phosphate synthase. The scope of the instant claims includes structurally related polynucleotides that are not necessarily functionally related. The specification has not enabled the use of structurally related polynucleotides, wherein the encoded polypeptides have a different function. No guidance or working examples are described for how to use structurally, but not functionally, related polynucleotides. The specification focuses on overexpressing the OtsA protein for the production of lysine in *C. glutamicum*; this use is not shown viable with a polynucleotide encoding a polypeptide not having OtsA protein function, trehalose 6-phosphate synthase. The nature of the invention is such the function of the encoded polypeptide is crucial to its use. Thus, in the absence of such a limitation, the instant claims are not enabled to the full extent of their scope.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-6, 10-22, 27, and 42-45 are rejected under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605 filed on December 18, 2000). Nakagawa *et al.* is related to EP 1108790, which is noted in the IDS of record). The instant claims are drawn to a polynucleotide that is SEQ ID NO:1, vectors and *C. glutamicum* host cells thereof as well as methods of using SEQ ID NO:1 to produce the encoded protein.

Nakagawa *et al.* teach SEQ ID NO:1 that is identical to SEQ ID NO:1 of the instant application from 2791990-2794999 base pairs (see attached alignment). Nakagawa *et al.* also teach vectors, specific host cells, and methods of making the protein (see pages 3 and 5).

18. Claims 16 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Pompejus *et al.* (WO 01/00843 published on January 4, 2001 – see IDS). The instant claims are drawn to a polynucleotide that is a fragment of SEQ ID NO:1 and that hybridizes to SEQ ID NO:1.

Pompejus *et al.* teach a 1578-mer fragment of SEQ ID NO:1 that is identical to SEQ ID NO:1 of the instant application in the range of 784-2361 base pairs (see attached alignment).

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The Examiner notes that the submission of translated foreign priority documents that contain support for the instant claims would render the instant rejection a 102(a)-type.

19. Claims 16 and 17 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ziegler *et al.* (USPN 6,410,705 filed November 1, 1999). The instant claims are drawn to a polynucleotide that is a fragment of SEQ ID NO:1 and that hybridizes to SEQ ID NO:1.

Ziegler *et al.* teach a polynucleotide (SEQ ID NO:1 from 1406-2817) that is identical to SEQ ID NO:1 of the instant application in the range of 1-1412 base pairs (see attached alignment).

#### ***Additional Art Cited***

20. The following are not rejections, but art cited by the Examiner so as to complete the record:

- a) USPAP 20020137150 filed July 2, 2001 (related to EP 1174508 which is cited on an IDS from Applicants). Ohtaki *et al.* teach a polynucleotide that is a 77% overall match to SEQ ID NO:1 with almost 100% identity in certain portions. Since this date and the match are not better than that of USPAP 20020197605 used in an art rejection above, Ohtaki *et al.* has not been used as prior art in a rejection herein.

#### ***Conclusion***

21. Claims 1-6, 10-22, 27, and 42-45 are not allowed for the reasons identified in the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Kathleen M Kerr  
Examiner  
Art Unit 1652

January 20, 2004